## DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION

## PROCESSING IN WATER IN DISCONTINUOUS AGITATING RETORTS (Retort Survey)

## **INSTRUCTIONS**

This report covers batch type agitating retort systems pressure processing in water with overriding air or steam. This includes the traditional rotating systems specifically covered under 113.40(e) as well as other axial and end-over-end processing systems not specifically covered by 113.40(e).

If deficiencies are found with the firm's retort equipment or processing system, refer the reader to the narrative Turbo EIR under "Objectionable Conditions and Management's Response" and include a narrative explanation of specific problems and evidence under the subheading "Supporting Evidence and Relevance". Submit the completed form as an EIR attachment.

Complete the question blocks below. Draw a diagram of the retort or obtain one from the firm. Attach the diagram to this survey report. Report all pipe sizes as inside diameter (ID). Refer to 21CFR Part 113.40(e) and pp 32-34 of LACF Guide Part 2.

		RETORT DESCRIP	TION		
RETORT NO.	*CAN SIZE	COOKER	R CAPACITY	STEPS/REEL	
	DD00E00INO MO				
	PROCESSING MC				
	Axial	End-over-End			
*List the container size covered d	luring the inspection.				
		COMPUTER CONTI	ROLS		
DOES A COMPUTER CONTR	ROL ANY OF THE R	ETORT FUNCTIONS?		Yes	No 🗌
EXPLAIN:				_	_
DOES THE FIRM HAVE DOC	UMENTATION ON F	IAND THAT INDICATES T	HAT THE COMPUTER SY	STEM HAS BEEN VAL	IDATED?
				Yes	No 🗌
EXPLAIN:					
IS RECORD KEEPING PART	OF THE COMPLITE	B FUNCTION?		Yes 🗆	No 🗆
					_
IF YES, DOES THE RECORD	KEEPING COMPLY	WITH 21 CFR PART 11?		Yes 📋	No 🗌
		AGITATION			
IS THE AGITATING RETORT	OPERATED IN THE	STILL MODE?		Yes	No 🗌
IF CRATES ARE USED, IS TH	HE CRATE POSITIO	N CRITICAL TO THE COM	//E-UP AND/OR PROCES	S? Yes 🗌	No 🗌

IF CRATE POSITION HAS BEEN DETERMINED CRITICAL TO THE PROCESS, WHAT IS THE RECOMMENDED POSITION AND HOW WAS IT DETERMINED? (FOR EXAMPLE, PROCESS ESTABLISHMENT TESTS MAY HAVE DETERMINED THAT AN ANGLED CRATE POSITION RESULTS IN FASTER HEAT PENETRATION.)

PROCESSING WATER	
METHOD USED TO HEAT PROCESS WATER:  A. Steam Injection Into Process Water   B. Heat Exchanger   C. Steam Spreader   D. Other   IF OTHER, EXPLAIN:	
WATER DRAINS	
ARE SCREENS USED OVER ALL DRAIN OPENINGS TO PREVENT CLOGGING OF DRAINS?	]
IS THE DRAIN LINE VALVE WATER TIGHT AND NON-CLOGGING	]
WATER DISTRIBUTION	
WATER DISTRIBUTION SYSTEM:	
Manifold Plate?Yes No	
Spray Nozzle Heads? Yes No	
Manifold Pipe? Yes No	
Other? Yes	
IF OTHER, EXPLAIN:	
DESCRIBE HOLE SIZE AND DISTRIBUTION IN MANIFOLD/SPRAY NOZZLES:	
HAVE HOLE SIZES BEEN ALTERED BY PRODUCT OR MINERAL BUILD-UP?	]
DOES THE FIRM HAVE A CLEANING PROGRAM FOR THE WATER DISTRIBUTION SYSTEM?	]
HOW DOES THE FIRM INSURE THAT WATER FLOW IS CONSTANT?	
Visual ChecksYes No	
Water Flow Measurement Yes No	
Flow Meter Yes No No	
HOW OFTEN IS WATER FLOW CHECKED?	
WHAT IS THE WATER FLOW RATE?	
DESCRIBE THE PROCEDURE TO INSURE WATER FLOW IS MAINTAINED:	
PROVIDE THE WATER FLOW METER MODEL NUMBER AND LOCATION:	

AT WHAT POINT DOES WATER ENTER THE RETORT WATER DISTRIBUTION SYSTEM?
Back TopYes  No
Back BottomYes No
Front TopYes No
Front Bottom Yes No
Center Yes
MultipleYes  No
EXPLAIN THE WATER DISTRIBUTION SYSTEM:
DESCRIBE THE WATER RETURN SYSTEM:
ARE WATER RETURN INLETS SCREENED?
IS THE PROCESSING WATER REUSED?
IF WATER IS REUSED DURING THERMAL PROCESSING, WHAT IS THE RECIRCULATION RATE?
WHAT IS THE CAPACITY OF THE WATER PUMP (GPM/LPM)?
IS WATER FLOW IDENTIFIED AND CONTROLLED AS A FACTOR CRITICAL TO THE THERMAL PROCESS? Yes No
ARE WATER FLOW PROBLEMS HANDLED AS PROCESS DEVIATIONS?
DURING THE INSPECTION, WAS THERE ANY EVIDENCE OF LOW WATER FLOW?
COOLING WATER SUPPLY
IS PROCESSING WATER USED TO COOL CONTAINERS DURING THE COOLING CYCLE?
IF WATER IS INTRODUCED FROM AN EXTERIOR SOURCE DURING COOLING, IS THE WATER COOLING LINE EQUIPPED WITH A CHECK VALVE?
INDICATING MERCURY IN-GLASS THERMOMETERS (113.40(e)(1))
IS THE RETORT EQUIPPED WITH AT LEAST ONE MERCURY-IN-GLASS (MIG) THERMOMETER?
IS THE RETORT EQUIPPED WITH A TEMPERATURE INDICATING DEVICE OTHER THAN A MERCURY-IN-GLASS THERMOMETER?

ARE SCALE DIVISIONS EASILY READABLE TO 1°F (.5°C)?	
STANDARD USED FOR THE TEST:	
NAME AND TITLE OF PERSON WHO PERFORMED TEST:	
IS THE LAST TEST DATE IDENTIFIED ON THE THERMOMETER?	
DESCRIBE THE FIRM'S ACTIONS REGARDING MIG THERMOMETERS THAT WERE OUT OF CALIBRATION:	
IS THE MERCURY UNDIVIDED?	
WHEN MIG THERMOMETERS ARE FOUND TO BE PROVIDING READINGS ABOVE THE ACTUAL TEMPERATURES, DOES THE FIRM EVALUATE PRODUCTS PRODUCED USING THOSE THERMOMETERS?	
IS THE THERMOMETER LOCATED WHERE IT IS EASY TO READ ACCURATELY?	
THE SENSOR BULB IS LOCATED IN THE	
IS THE MERCURY THERMOMETER USED AS THE REFERENCED INSTRUMENT DURING PROCESSING? Yes No (SHALL REQUIREMENT)	
TEMERATURE RECORDER (113.40(e)(2))	
TYPE OF TEMPERATURE RECORDER	
DO THE CHART SPECIFICATIONS MEET THE REQUIREMENTS OF PART 113.40(e)(2)?	
(SHALL REQUIREMENT; NOTE ANY DIFFERENCE BETWEEN THE RECORDING THERMOMETER AND THE MERCURY-IN-GLASS THERMOMETER AND WHICH READING IS HIGHER.)	

IS THERE A MEANS FOR PREVENTING UNAUTHORIZED ADJUSTMENTS?
(A MEANS OF PREVENTING UNAUTHORIZED CHANGES IN ADJUSTMENTS <u>SHALL</u> BE PROVIDED. A LOCK OR NOTICE FROM MANAGEMENT STATING "ONLY AUTHORIZED PERSONS ARE PERMITTED TO MAKE ADJUSTMENTS" & POSTED AT OR NEAR THE RECORDING DEVICE IS A SATISFACTORY MEANS FOR PREVENTING UNAUTHORIZED CHANGES.)
IS THE CHART DRIVE TIMING MECHANISM ACCURATE?
IS THE RECORDER COMBINED WITH A TEMPERATURE (STEAM) CONTROLLER TO FUNCTION AS A RECORDING/ CONTROLLING INSTRUMENT?
TEMPERATURE CONTROLLER
HOW IS TEMPERATURE CONTROLLED IN THE RETORT?
Recorder Controller
REPORT THE MANUFACTURER, MODEL, TYPE AND SIZE OF THE AUTOMATIC STEAM CONTROL VALVE:
IF THE TEMPERATURE (STEAM) CONTROLLER IS AIR OPERATED, DOES THE SYSTEM HAVE AN ADEQUATE FILTER TO ASSURE A SUPPLY OF CLEAN, DRY AIR?
COME-UP PROCEDURE
DESCRIBE THE FIRM'S PROCEDURE TO BRING THE RETORT UP TO PROCESSING TEMPERATURE. INCLUDE TIME, TEMPERATURE AND NUMBER OF STEPS:
CAN THE FIRM DOCUMENT ALL STEPS OF THE COME-UP PROCEDURE?
DOES THE FIRM IDENTIFY PROCESS COME-UP STEPS AS CRITICAL ON THE PROCESSING FILING FORMS?  Yes No No
(NOTE: PROCESSING STEPS ARE REQUIRED ON THE PROCESS FILING FORM WHEN THEY HAVE BEEN IDENTIFIED AS CRITICAL TO THE THERMAL PROCESS. THIS IS ALWAYS THE CASE WHEN THE GENERAL METHOD IS USED TO CALCULATE THE ${\it F}_{\it o}$ .)
AIR PURGE
IN SOME SYSTEMS AN AIR PURGE (VENT VALVE) IS USED TO ENHANCE WATER ENTRY INTO THE PROCESSING VESSEL; IS AN AIR PURGE VALVE USED ON THE PROCESSING VESSEL?
HAS TIMING OF THE AIR PURGE VALVE (TIME OPEN) BEEN IDENTIFIED AS CRITICAL TO ADEQUATE TEMPERATURE DISTRIBUTION IN THE RETORT?
HEATED PROCESS WATER
IS WATER PREHEATED IN A SEPARATE VESSEL PRIOR TO PROCESSING?

IS THE WATER TEMPERATURE OF THE PREHEATED WATER CRITICAL TO TEMPERATURE DISTRIBUTION IN THE RETO	ORT?
Yes	No 🗌
DESCRIBE THE TEMPERATURE REQUIREMENTS FOR PREHEATED WATER:	
DID THE FIRM MEET THE REQUIREMENTS FOR PREHEATING WATER DURING THIS INSPECTION? Yes   EXPLAIN:	No 🗌
TEMPERATURE DISTRIBUTION	
HAVE TEMPERATURE DISTRIBUTION STUDIES BEEN PERFORMED ON THE FIRM'S RETORTS?	No 🗌
DATE OF LAST TEMPERATURE DISTRIBUTION STUDY:	
HAS A TEMPERATURE DISTRIBUTION STUDY BEEN PERFORMED ON EACH INDIVIDUAL RETORT? Yes	No 🗌
HAS A TEMPERATURE DISTRIBUTION STUDY BEEN PERFORMED ON EACH CONTAINER SIZE? Yes	No 🗌
HAS A TEMPERATURE DISTRIBUTION STUDY BEEN PERFORMED ON EACH CONTAINER TYPE? (E.G., GLASS, METAL, PLASTIC)	, No 🗌
HAS A TEMPERATURE DISTRIBUTION STUDY BEEN PERFORMED ON EACH PRODUCT OR PRODUCT TYPE?  Yes	No 🗌
HAVE TEMPERATURE DISTRIBUTION STUDIES BEEN PERFORMED TO DETERMINE THE EFFECTS OF TEMPERATURE DROPS DURING COME-UP AND PROCESSING?	E No 🗌
ARE PARTIAL LOADS PROCESSED IN THE FIRM'S RETORTS?	No 🗌
RETORT CRATES & RACKS	
DESCRIBE THE RETORT CRATES:  DIMENSIONS:  NUMBER OF HOLES:	
SIZE OF HOLES:	
LOCATION OF HOLES:	
CRATES/BASKETS NOT USED	
ARE CONTAINERS POSITIONED IN THE RETORT AS SPECIFIED IN THE SCHEDULED PROCESS?	No 🗌
ARE DIVIDERS, TRAYS, RACKS OR OTHER MEANS OF POSITIONING FLEXIBLE CONTAINERS DESIGNED AND EMPLOINSURE EVEN CIRCULATION OF HEATING MEDIUM AROUND ALL CONTAINERS?	YED TO No

ARE DIVIDER PLATES USED?
DESCRIBE NUMBER OF HOLES AND DISTRIBUTION IN DIVIDER PLATES:
IS THE SAME TYPE OF DIVIDER PLATE USED FOR ALL CONTAINERS?
ARE CONTAINERS PROCESSED WITHOUT DIVIDER PLATES?
CONTAINER NESTING WHERE ONE CONTAINER OR MORE ARE POSITIONED ONE INSIDE ANOTHER TO REPRESENT A MUCH LARGER CONTAINER MAY OCCUR WITH PRODUCTS DESIGNED TO STACK ON STORE SHELVES E.G. TUNA, SARDINES.
IS CONTAINER NESTING POSSIBLE?
HOW DOES THE FIRM CONTROL NESTING OF CONTAINERS?
WAS CONTAINER NESTING EVALUATED AS PART OF THE PROCESS ESTABLISHMENT
WHICH OF THE FOLLOWING CONTAINER TYPES ARE PROCESSED?
Metal Cans Glass Jars Pouches Rigid Plastic
DOES THE FIRM PROCESS MORE THAN ONE CONTAINER SIZE?
METAL CANS
GLASS JARS
POUCHES
RIGID PLASTIC
IF MORE THAN ONE CONTAINER SIZE OR TYPE IS PROCESSED AT ONE TIME, DESCRIBE PROCEDURES USED:
FOR POUCHES, ARE TRAYS ADEQUATELY DESIGNED WITH POCKETS TO CONTAIN AND RESTRAIN INDIVIDUAL POUCHES
DURING PROCESSING?
ARE TRAYS OR DIVIDER PLATES IN GOOD CONDITION WITH NO SHARP OR ROUGH POINTS THAT COULD PUNCTURE CONTAINERS?Yes No No
PRESSURE CONTROL
ARE PRODUCTS PRODUCED USING OVERPRESSURE?
IF YES, WHAT OVERPRESSURE IS ACHIEVED?
IO THE DETORT FOUNDED WITH A DEFOUNDE CASES
IS THE RETORT EQUIPPED WITH A PRESSURE GAGE?
IS A MEANS PROVIDED FOR INTRODUCING COMPRESSED AIR OR STEAM AT THE PROPER PRESSURE AND RATE?
Yes □ No □
ICTUE PRECOURE IN THE RETORT CONTROLLED BY AN AUTOMATIC PRECOURT CONTROLLED BY THE
IS THE PRESSURE IN THE RETORT CONTROLLED BY AN AUTOMATIC PRESSURE CONTROL UNIT?
( <u>SHALL</u> REQUIREMENT)

IF A PRESSURE GAGE IS PRESENT ON THE RETORT COOKER SHELL, IS IT GRADUATED IN DIVISIONS OF 2 LBS. OR LESS?
Yes No No
(NOTE: THIS IS A RECOMMENDATION – "SHOULD" REQUIREMENT – 113.40(e)(3).)
DESCRIBE THE LOCATION WHERE COMPRESSED AIR OR STEAM ENTERS THE RETORT:
IS COMPRESSED AIR USED FOR OVERPRESSURE HEATED PRIOR TO INTRODUCTION INTO THE RETORT?
Yes No N/A
IS A DIFFUSER USED ON THE COMPRESSED AIR ENTRY LINE TO INSURE RAPID MIXING OF THE AIR IN THE RETORT ATMOSPHERE?
HAS THE POINT WHERE AIR ENTERS THE RETORT BEEN IDENTIFIED AS A COLD SPOT IN THE RETORT?
Yes No N/A
EXPLAIN HOW PRESSURE IS CONTROLLED IN THE RETORT:
HAS OVERPRESSURE BEEN IDENTIFIED AS CRITICAL TO THE THERMAL PROCESS?
ARE PRESSURE DROPS CONSIDERED PROCESS DEVIATIONS?
WHY NOT?
RETORT SPEED TIMING (113.40(e)(5))
IS THE ROTATIONAL SPEED OF THE RETORT SPECIFIED IN THE SCHEDULED PROCESS?
IS THE ROTATIONAL SPEED OF THE RETORT ADJUSTED, AS NECESSARY, TO ENSURE THAT THE SPEED IS AS SPECIFIED IN THE SCHEDULED PROCESS?
(SHALL REQUIREMENT)
IS THE ROTATIONAL SPEED OF THE RETORT AND THE PROCESS TIME RECORDED FOR EACH RETORT LOAD PROCESSED?
PROCESS TIME
ROTATIONAL SPEED
(SHALL REQUIREMENT)
IF NO, IS A RECORDING TACHOMETER USED TO PROVIDE A CONTINUOUS RECORD OF THE SPEED? Yes No
(SHALL REQUIREMENT)
IF NO TO THE ABOVE 2 QUESTIONS, HOW DOES THE FIRM MONITOR AND RECORD THE RETORT SPEED AND PROCESS TIME OF EACH RETORT LOAD PROCESSED?

DOES THE FIRM HAVE A MEANS OF PREVENTING UNAUTHORIZED SPEED CHANGES ON THE RETORT? Yes No (SHALL REQUIREMENT; A LOCK OR NOTICE FROM MANAGEMENT POSTED AT OR NEAR THE SPEED ADJUSTMENT DEVICE THAT PROVIDES A WARNING THAT ONLY AUTHORIZED PERSONS ARE PERMITTED TO MAKE ADJUSTMENTS, IS A SATISFACTORY MEANS OF PREVENTING UNAUTHORIZED CHANGES.)
EXPLAIN HOW THE RETORT ROTATIONAL SPEED IS MONITORED AND RECORDED:
OTHER CONCERNS AND OBSERVATIONS  EVALUATION AND OTHER CONCERNS WITH THE OPERATION OF THIS RETORT SYSTEM: